510(K) SUMMARY

JUN 0 5 2013

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is K122020.

1. Submitter's Identification:

ZOLAR TECHNOLGY & MFG CO. INC.
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MISSISSAUGA, ON, L5T 1H8, CANADA

Contact:

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Date Summary Prepared: June 3, 2013

2. Name of the Device:

Photon/Photon Plus
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX

3. Common or Usual Name:

Dental Diode Laser

4. Predicate Device Information:

Picasso/Picasso Lite Dental Diode Lasers, K102359

stLase Dental Laser, K111689

5. Device Description:

The Photon/Photon Plus is intended for use by dentists in oral soft tissue and tooth whitening procedures.

Photon/Photon Plus Diode Laser is a surgical device at the cutting edge of technology, designed for a wide variety of oral soft tissue and tooth whitening procedures with the wavelength of 980nm and the power range of 100mW to 10W.

Photon Series Diode Laser utilizes a solid state diode a laser energy source. The energy is delivered to the operating area by means of a delivery system consisting of a flexible fiber connecting the laser source and the handpiece. The device is activated by means of a footswitch.

6. Intended Use:

The Photon is intended for use by dentists for excision, incision, vaporization, ablation and coagulation of oral soft tissue procedures. The specific applications are as follows:

SOFT TISSUE: The metal handpiece with cutting fiber does not have any direct contact to the soft tissue, skin or cell during the operation.

- Exposure of Unerupted teeth
- Fibroma removal
- Frenectomy
- Gingival Troughing for crown impressions
- Gingivectomy
- Gingivoplasty
- Hemostasis and coagulation
- Gingival incision and excision hemostasis
- Implant recovery
- Incision and drainage of abscess
- Leukoplakia
- Operculectomy
- Oral papillectomies
- Pulpotomy as an adjunct to root canal therapy
- Reduction of gingival hypertrophy
- Soft tissue crown lengthening
- Gingival bleeding index
- Excisional and incisional biopsies
- Treatment of aphthous ulcer, canker sores and herpetic
- Vestibuloplasty.

LASER PERIODONTAL PROCEDURES:

- Sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket to improve clinical indices including:, probe depth, attachment loss and tooth mobility)
- Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium

Indications for Use for Photon Plus:

The Photon Plus is intended for use by dentists for excision, incision, vaporization, ablation and coagulation of oral soft tissue procedures. The specific applications are as follows:

SOFT TISSUE: The metal handpiece with cutting fiber does not have any direct contact to the soft tissue, skin or cell during the operation.

- Exposure of Unerupted teeth
- Excision of lesion or removal of Granulation tissue
- Frenectomy
- Gingival Troughing for crown impressions
- Gingivectomy
- Gingivoplasty
- Hemostasis and coagulation
- Gingival incision and excision hemostasis
- Implant recovery
- Incision and drainage of abscess
- Leukoplakia
- Operculectomy
- Oral papillectomies
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- Reduction of gingival hypertrophy
- Soft tissue crown lengthening
- Gingival bleeding index
- Excisional and incisional biopsies
- Treatment of aphthous ulcer, canker sores and herpetic
- Vestibuloplasty.

LASER PERIODONTAL PROCEDURES:

- Sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket to improve clinical indices including:, probe depth, attachment loss and tooth mobility)
- Debridement of diseased epithelial lining

TOOTH WHITENING INDICATIONS

- Laser assisted whitening/bleaching of teeth
- Light activation for bleaching materials for teeth whitening.

7. Comparison to Predicate Devices:

The subject device is of a comparable type and substantially equivalent to the previously licensed Picasso and Picasso Lite marketed by AMD Lasers LLC and the stLase by Dental Photonics, Inc.
To facilitate the comparison, the principal features of the subject devices are listed side-by-side with the predicate devices. Refer to the comparison table shown below:

Zolar Photon Plus and Stlase IFU Comparison Chart

Zolar Photon Plus (subject)	St Lase Predicate (K111689)
Exposure of Unerupted teeth	incision, excision, vaporization, ablation,
Excision of lesion or removal of Granulation tissue	removal of granulation tissue,
Frenectomy	
Gingival Troughing for crown impressions	Frenectomy, Frenotomy,
Gingivectomy	gingival troughing, crown lengthening,
Gingivoplasty	gingivectomy,
Hemostasis and coagulation	gingivoplasty,
Gingival incision and excision hemostasis	hemostasis, or coagulation of intraoral and extraoral soft tissue (including marginal and interdental gin giva and epithelial lining of free gin giva)
Implant recovery	implant recovesry/uncovery,
Incision and drainage of abscess	incisions and draining of abscesses
Leukoplakia	Leukoplakia
Operculectomy	operculectomy
Oral papillectomies	papillectomy
Pulpotomy as an adjunct to root canal therapy	pulpotomy as an adjunct to root canal therapy
Reduction of gingival hypertrophy	papillectomy
Soft tissue crown lengthening	
Gingival bleeding index	crown lengthening
Excisional and incisional biopsies	gingival troughing
	biopsy
Treatment of aphthous ulcer, canker sores and herpetic	
Vestibuloplasty.	Treatment of aphthous ulcers
LASER PERIODONTAL PROCEDURES:	vestibuloplasy,
Sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket to improve clinical indices including:, probe depth, attachment loss and tooth mobility)	dental soft tissue indications including: incision, exci sion, vaporization, ablation, biopsy, removal of granulation tissue, laser assisted flap surgery, debridement of diseased epithelial lining, , tissue retraction for impressions, , excision of lesions, leukoplakia, removal of hyperplastic tissues, and removal of hyperplastic tissues, , sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket),. and light activation of bleaching materials for teeth whitening
Debridement of diseased epithelial lining	
TOOTH WHITENING INDICATIONS	
Laser assisted whitening/bleaching of teeth	
Light activation for bleaching materials for teeth whitening.	

Zolar Photon and Picasso IFU Comparison Chart

Zolar Photon(subject)	Picasso Predicate(K102359)
Exposure of Unerupted teeth Fibroma removal Frenectomy Gingival Troughing for crown impressions Gingivectomy Gingivoplasty Hemostasis and coagulation Gingival incision and excision hemostasis Implant recovery Incision and drainage of abscess Leukoplakia Operculectomy Oral papillectomies Pulpotomy as an adjunct to root canal therapy Reduction of gingival hypertrophy Soft tissue crown lengthening Gingival bleeding index Excisional and incisional biopsies Treatment of aphthous ulcer, canker sores and herpetic Vestibuloplasty. LASER PERIODONTAL PROCEDURES: Sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket to improve clinical indices including:, probe depth, attachment loss and tooth mobility) Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium	Exposure of unerupted teeth Fibroma removal Frenectomy and frenotomy Gingival troughing for crown impression Gingivectomy Gingivoplasty Hemostasis and coagulation Gingival incision and excision Implant recovery Incision and drainage of abscess Leukoplakia Operculectomy Oral papillectomnies Pulpotomy as an adjunct to root canal therapy Reduction of gingival hypertrophy Soft tissue crown lengthening Gingival bleeding index, probe depth, attachment loss, and tooth mobility Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa Vestibuloplasty Excisional and incisional biopsies Sulcular debridernent (curettage, removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including: gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility). Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium. Picasso assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium).

Comparison of Stlase and Zolar Photon Plus (Technical Specifications)

Specifications	**Dental Photonics StLase (K111689)**	**Zolar--Photon Plus (Subject Device)**
Wavelength	980 nm	980nm
Power	25 w	10 W
Power range	0.5-25w	100mW to 10W
Increments	0.1-0.5w	0.1 w
Operating modes	Pulsed or CW	Pulsed or CW
Amining beam	650 nm, 5mW	650nm, 2 mW
Cooling	Air cooled, closed control water	Air cooled
Weight	around 1.8 KG	around 1.2 KG
Power requirements	120v/60 HZ or 240 V/50HZ	120v/60 HZ or 240 V to charge-Battery
Sterilization method	Steam autoclave	Steam autoclave
Physical Media Source	Diode	Diode
Wattage	0.5 to 25 watts	0.1 to 10 watts
Control Panel	Color Touch screen	Colour Touch screen
Settings	-	22 Treatable & 3 customizable
Frequency	20,000Hz	1-5000Hz
Pulse Interval	0.025ms – 3ms	0.1ms-9.9s
Pulse Energy	Continuouse & Pulse Modes	Continuouse & Pulse Modes
Laser Clasification	Class 4	Class 4
Aiming Beam	650nm, 5mW	3 levels of Intensity
Foot Switch Operation	-	Yes
Dental Applications	Deatal Soft Tissue indications; General surgey for incision/excision, vaporazation; abalation and coagulation of soft tissues; Dental laser operation incl. light activation of bleathing materils for tooth whitenting.	Soft Tissue Surgery Periodontal & Hygiene Endodontic, Whitening / Bleaching.
Autoclave	Hand Piece Autoclavable	Hand Piece Autoclavable

Comparison of Picasso/Picasso Lite and Zolar Photon Plus/Photon (Technical Specifications)

Specifications	**Picasso Lite/Picasso (K102359)**	**Zolar—Photon/Photon Plus (Subject Device)**
Physical Media Source	Diode	Diode
Wattage	0.1 to 2.5 watts / 0.1 to 7 watts	0.1 to 3.0W / 0.1 to 10 watts
Wavelength nm	810 nm	810 nm/980 nm
Control Panel	Color Touch Screen / Universal Icon Membrane Touch screen	Color Touch screen
Settings	8 Treatable (prest values) / Manual	22/23 Treatable & customizable
Pulse Energy	Continuous & Pulse Modes	Continuous & Pulse Modes
Delivery Fiber Diameter	200-1000um	200-1000um
Laser Classification	Class 4	Class 4
Aiming Beam	Variables (adjustable)	Variables (3 settings)
Foot Switch Operation	Yes	Yes
Audible/Visual Notification	Yes	Yes
Autoclave	Hand Piece Autoclavable	Hand Piece Autoclavable
Applicable standards	IEC 60825-1 IEC 60601-2-22	IEC 60825-1 IEC 60601-2-22

The Photon Plus / Photon Dental Diode Lasers are of a comparable type and substantially equivalent to the currently marketed Picasso / Picasso Lite (K102359) and stLase Dental Lasers (K111689). Although the subject devices are somewhat smaller and lighter than Picasso devices, the overall construction, materials and performance as well as key features are equivalent. The subject devices have the same intended uses as the predicate devices and the Photon Plus subject device includes features which are well established on the stLase Dental Laser systems.

8. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The subject devices have been tested for thermal, electrical and mechanical safety, and conform to applicable medical device safety standards, IEC 60825-1 and IEC 60601-2-22.

Testing was conducted to validate and verify that the Photon/Photon Plus devices met all design specifications and were substantially equivalent to the predicate devices.

Photon/Photon Plus have also been tested to assure compliance to the requirements of various published standards, including ANSI/AAMI ST79, AAMI TIR 12, ANSI/AAMI/ISO 17665-1, ANSI/AAMI ST77, ANSI/AAMI ST81, ISO 17664, ANSI/AAMI ST67, ANSI/AAMI ST8, EN 556.

9. Discussion of Clinical Tests Performed:

Not Applicable

10. Conclusion:

We have demonstrated that there are no significant differences between the subject devices, and the predicate devices, Photon/Photon Plus and the predicate devices, Picasso/Picasso Lite Dental Diode Lasers, K102359, and stLase Dental Laser, K111689, in terms of safety and effectiveness based on electrical, mechanical and environmental test results. Based on this information, the 8subject devices are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Zolar Technology & Mfg. Co., Inc.
% MDI Consultants, Inc.
Ms. Susan D. Goldstein-Falk
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Letter dated: June 5, 2013

Re: K122020
Trade/Device Name: Photon/Photon Plus
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general surgery and Plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: May 17, 2013
Received: May 20, 2013

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122020

Device Name: Photon/Photon Plus

Indications for Use for Photon:

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SOFT TISSUE: The metal handpiece with cutting fiber does not have any direct contact to the soft tissue, skin or cell during the operation.

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LASER PERIODONTAL PROCEDURES:

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- Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium

Neil R Ogden
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(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number __K122020_____

Indications for Use for Photon Plus:

The Photon Plus is intended for use by dentists for excision, incision, vaporization, ablation and coagulation of oral soft tissue procedures. The specific applications are as follows:

SOFT TISSUE: The metal handpiece with cutting fiber does not have any direct contact to the soft tissue, skin or cell during the operation.

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- Leukoplakia
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- Oral papillectomies
- Pulpotomy as an adjunct to root canal therapy
- Reduction of gingival hypertrophy
- Soft tissue crown lengthening
- Gingival bleeding index
- Excisional and incisional biopsies
- Treatment of aphthous ulcer, canker sores and herpetic
- Vestibuloplasty

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(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number ___K122020_____

LASER PERIODONTAL PROCEDURES:

- Sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket to improve clinical indices including:, probe depth, attachment loss and tooth mobility)
- Debridement of diseased epithelial lining

TOOTH WHITENING INDICATIONS

- Laser assisted whitening/bleaching of teeth
- Light activation for bleaching materials for teeth whitening.

Prescription Use __x__ **OR** **Over-The Counter Use_____**
(Per 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

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Neil R Ogden -S
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(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number ___K122020_____